

Food Labeling: Use on Dietary Supplements of Health Claims Based on
Authoritative Statements

Department of Health and Human Services 1577 '99 MAR 24 P1 56

Agency: Food and Drug Administration, HHS
Action: Comment
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I agree with the Food and Drug Administration's proposal to permit dietary supplements to be subjected to the same standards and procedures as conventional foods. If the dietary supplement industry makes health claims regarding the use of their products they should also be subjected to notification procedures by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Since FDAMA permits nutrient content claims based on authoritative statements for conventional foods and dietary supplements it would be beneficial to consumers for FDAMA to provide for the use of health claims based on authoritative statements for dietary supplements. This rule is extremely important due to the fact that many consumers are not aware of the ingredients contained in dietary supplements. Many are willing to buy products with misleading health claims on the labels which could be potentially harmful or may not have any effect on the consumer whatsoever which would be an absolute waste of their hard earned money.

Many manufacturers are willing to capitalize on the fact that some consumers are unaware. According to A *New York Times* article by Constance L. Hays, "soup style supplements...are among dozens of foods, or foodlike products, landing on the market to capitalize on America's soaring enthusiasm for food that goes beyond ordinary nutrition.

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No longer content with fortifying products with vitamins or minerals, food companies are starting to add herb-based substances that purport to offer particular health benefits that in some cases have not been proved."¹ If manufacturers are required to provide scientific literature stating the nutrient level or the relationship between the nutrients and the disease or health-related condition, consumers will be more able to make informed choices based on the supplement labeling. Also, since the scientific claims must be published either by a trusted "scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition," manufacturers of supplements will be forced to validate their health claims before placing them on supplement labels. I also agree with the benefit cost analysis, which states that consumers will benefit from the availability of the information provided by health claims.

"Consumers have started to see a variety of interpretations, ranging from older foods repackaged with claims on labels, to foods with substances like herbal extracts added. Herbs like St. John's Wort, touted as a mild anti-depressant, and ginkgo, advertised as aiding memory, are turning up in cereals, soups and snacks. Companies see the interest in herbal medicine as a new way to sell old products."²

Hays gave an example of a can of Hain Pure Foods Kitchen Prescription Herbal Supplement whose label says "'Support your immune system* with a cup of Kitchen Prescription today! The asterisk leads to this postscript: 'this statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.'" With labels like these, consumers will be able to read the package and make decisions regarding their purchase and use of these

¹ Constance L. Hays. "It's Not Just Food, It's A Supplement". *New York Times*. February 9, 1999 D6-D7.

² Hays D6-D7

products. If manufacturers receive the correct documentation from the appropriate government body, they will be more likely to gain the consumer's trust if they have proven and truthful labels on their products. This practice will not only benefit the consumer but the manufacturer and also society. Hays gave a good example from a Quaker represent of Quaker Oats Cereal Company which invested their time and money and obtained FDA approval for "claiming that its oatmeal contained nutrients that could lower cholesterol. The process included compiling research and sponsoring clinical trials. Two years later, Quaker was cleared to add the cholesterol-lowering claim... With news of the health benefit circulating, sales rose 5 percent... The next year with the claim on the package, sales rose another 6 to 7 percent." ³

Consumers will be able to save time by not having to search for information before or after they purchase the supplements and will be able to save money if they are not purchasing supplements with phony health claims. This is proof that approved food labeling is beneficial to all involved.

I firmly believe that this proposed rule would have practical utility not only for the FDA but for manufacturers and consumers as well.

³ Hays D6-D7

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